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John R. Burke
President

August 22, 2005

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

**RE: Draft Report of the Threshold Working group, CFSAN:
Approaches to Establish Thresholds for Major Food Allergens and for Gluten in
Food.
FDA Docket No. 2005N-0231
70 Fed. Reg. 35258 (June 17, 2005)**

These comments are submitted by the Foodservice & Packaging Institute with sincere apology for having missed the Agency's August 16 deadline for comment. If we could think of a good excuse for missing the deadline, we would provide it. The date for comment just slipped past us. We apologize.

The Foodservice & Packaging Institute is the material-neutral national trade association for manufacturers and suppliers of single-use packaging used in foodservice applications.

The Institute is writing to say that we agree with FDA's assertion that requiring declaration of every *de minimis* amount of an allergen in food could produce consumer confusion and be contrary to the purposes of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), and the Congress and the Agency's stated goal of protecting public health. In that same spirit, the Institute requests FDA to exempt food packaging and food-contact substances from the scope of this labeling requirement if they should contain *de minimis* levels of such allergens.

In the case of single-use packaging, or single-use food-contact substances, we do not know of any reported incidence of these items being cited as causing an allergenic reaction in the hundred year history of the industry. We question, therefore, the value to consumers of labeling food packaging or food-contact substances for a *de minimis* amount of an allergen which may be present in these types of materials.

We urge the Agency to exclude food contact materials, and food packaging in general from the scope of FALCPA regulation.

Respectfully,

A handwritten signature of John R. Burke in dark ink, written over the word "Respectfully,".

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